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CERTIFIED MAIL - RETURN RECEIPT REQUESTED

April 22, 2003

Dr. Inés Triay, Manager
Carlsbad Field Office
Department of Energy
P.O. Box 3090
Carlsbad, New Mexico 88221-3090

Dr. Steven Warren, President
Washington TRU Solutions LLC
P.O. Box 2078
Carlsbad, New Mexico 88221-5608

RE: NMED COMMENTS ON THE ARGONNE NATIONAL LABORATORY – EAST/CENTRAL CHARACTERIZATION PROJECT FINAL AUDIT REPORT, AUDITS A-02-03 AND A-03-13
WASTE ISOLATION PILOT PLANT
EPA I.D. Number NM4890139088

Dear Drs. Triay and Warren:

On March 6, 2003, NMED received the initial Certification Audit Report of the Argonne National Laboratory – East/ Central Characterization Project (**ANL-E/CCP**) Audit Numbers A-02-03 and A-03-13 (**Audit Report**), from the Department of Energy's Carlsbad Field Office (**CBFO**). CBFO and Washington TRU Solutions LLC (**the Permittees**) were required to submit this Audit Report under the Waste Isolation Pilot Plant (**WIPP**) Hazardous Waste Facility Permit as specified in Permit Condition II.C.2.c. The intended scope of these initial certification audits was to ensure the adequacy, implementation, and effectiveness of the ANL-E/CCP waste characterization processes for retrievably stored debris and homogeneous solids contact-handled waste relative to the requirements of the WIPP Permit. The Audit Report consisted of the following items:

- A narrative report
- Completed copies of relevant Permit Attachment B6 checklists
- Final ANL-E/CCP standard operating procedures (electronic and hardcopy)
- Corrective action reports and items corrected during the audit

- Objective evidence examined during the audit
  - General information
  - Acceptable knowledge
  - Headspace gas
  - Real time radiography
  - Visual examination

NMED representatives observed the two ANL-E/CCP audits, A-02-03 on September 9-12, 2002, and A-03-13 on February 10-13, 2003. NMED has examined the Audit Report for evidence of compliance with the requirements of Permit Conditions II.C.2 (Audit and Surveillance Program) and II.C.1 (Waste Analysis Plan [**WAP**]). Between the two audits, the Audit Report indicates there were five WAP-related conditions adverse to quality requiring the issuance of CBFO corrective action reports that were corrected prior to submittal of the Audit Report; seven deficiencies requiring only remedial actions that were corrected during the audit; five observations identifying conditions that, if not controlled, could result in conditions adverse to quality; and eleven recommendations identifying opportunities for improvement. Attached are NMED's comments based upon observation of the ANL-E/CCP audits and review of the submitted information.

NMED notes that the scope of both audits, as provided to NMED in official notifications (dated July 1 and August 21, 2002 for A-02-03 and January 8, 2003 for A-03-13), identified "Nondestructive Examination – Digital Radiography/ Computed Tomography" (**DR/CT**) as a technical activity to be audited. While NMED believes it can be appropriate for the Permittees to reduce the scope of an audit if a site is unprepared for a certain technical activity, it is inappropriate to switch or add technical elements without prior notice. The inclusion of real time radiography (**RTR**) in the scope of audit A-03-13 was only informally implied when the audit team leader e-mailed procedural checklists to NMED staff on January 23, 2003, roughly two weeks prior to the audit. However, the substitution of RTR for DR/CT was not clearly evident until after the NMED observers arrived at the audit on February 10, 2003. The only formal notification of RTR being in the scope of the audit, and DR/CT being removed, is provided after the fact in Section 2.1 of the Audit Report. NMED recommends that the Permittees implement a formal procedure for notifying regulators when the scope of an audit changes, particularly when it involves adding or substituting a technical activity. This would not only clarify NMED's incoming expectations with respect to an audit, but also ensure the administrative record is complete and accurate with respect to the actual audit scope. This would also assist NMED in identifying appropriate staff to attend the audit, securing necessary travel arrangements, and the like, prior to an audit.

NMED concludes that the Audit Report is incomplete in that is does not adequately address all elements examined during the audit. Because of this incompleteness, NMED is withholding approval of the Permittees' Final Audit Report for ANL-E/CCP Audits A-02-03 and A-03-13 until the Permittees submit the additional information identified in the attached comments that demonstrate full implementation of all relevant permit requirements. Indicate revisions to any text in the Audit Report and checklists with redline/strikeout annotation.

NMED underscores that this withholding of approval is not related in any way to potential technical problems or issues with DR/CT. Rather, it is intended to ensure a complete record of all audit activities.

If you have any questions regarding this matter, please contact me at (505) 428-2512.

Sincerely,

James P. Bearzi
Chief
Hazardous Waste Bureau

JPB:soz

Attachment

cc: Steve Zappe, NMED HWB
Tracy Hughes, NMED OGC
Gordon Appel, IDNS
John Riekstins, IL EPA
Laurie King, EPA Region 6
Betsy Forinash, EPA ORIA
Connie Walker, Trinity Engineering
Matthew Silva, EEG
Don Hancock, SRIC
Joni Arends, CCNS
Lindsay Lovejoy, NMAGO
File: Red WIPP '03

NMED COMMENTS ON THE ARGONNE NATIONAL LABORATORY – EAST/ CENTRAL CHARACTERIZATION PROJECT (ANL-E/CCP) INITIAL CERTIFICATION AUDIT REPORT A-02-03 AND A-03-13

NMED's review indicated that this Audit Report showed less attention to detail than presented in previous Audit Reports and, unless remedied, this less rigorous approach to preparation could result in significant deficiencies in future Audit Reports. The body of the Audit Report appears to generally address the applicable elements. However, there are some omissions, errors, and inconsistencies including but not limited to the following items:

1. Please provide this and all future Audit Reports and B6 Checklists in electronic format (MS Word, WordPerfect, Adobe Acrobat, etc.). Obviously, CAR resolutions, objective evidence, etc., will continue to be available only in paper format. Providing information that is already available electronically will expedite review by readily allowing dissemination among NMED staff and contractors.

2. The information and objective evidence associated with CAR-02-087 (Tab CAR1) is generally repeated in Tab CAR2, which deals with CAR-02-088; likewise, Tab CAR2 (CAR-02-088) contains much repeated documentation associated with CAR-02-087. Tabs CAR3 and CAR4 also contained substantial duplicate information. The Permittees could exercise greater care in assembling only the relevant objective evidence associated with each CAR without duplicating large portions of draft procedures, etc. This would reduce the volume of the report and aid the reviewers in identifying relevant evidence documenting the closure of each CAR.

3. The manner in which DR/CT findings were excluded from the Audit Report is unacceptable. Despite the fact that the audit team identified numerous concerns during audit A-02-03 regarding DR/CT (i.e., CAR-02-092, one CDA, two observations, and one recommendation), descriptions of these concerns have been expunged from the Audit Report on the basis of the Permittees' decision to not request approval for this system from NMED.

   NMED has repeatedly urged the Permittees to produce Audit Reports that accurately reflect **all** relevant findings identified during audit activities. There is nothing in Permit Attachment B6 (Waste Isolation Pilot Plant Permittees' Audit and Surveillance Program) generally, or in Section B6-4 (Audit Conduct) specifically, that limits the Audit Report to only those activities for which the Permittees request NMED approval. Section B6-4 says, in relevant part:

   > "A formal final audit report will be provided to NMED which will include WAP-related CAR resolution results and audit results that will include, as a minimum, sections describing the scope, purpose, summary of deficiencies, and observations in narrative format, completed audit checklists, audited procedures, and other applicable documents which provide evidence of WAP implementation."

The Permittees must revise Sections 6 and 7 of the Audit Report to describe all CARs, CDAs, observations, and recommendations associated with DR/CT identified during Audit A-02-03, provide additional Tabs for the CAR and CDA, and update any other relevant sections in the Audit Report to reflect this information. The Permittees may qualify this additional information submittal with a statement indicating that approval for DR/CT is not requested.

4. As noted in the cover letter, the published scope for either of the ANL-E/CCP audits did not include RTR. As a result, the administrative record regarding the audits at ANL-E is incomplete in this matter. Develop and implement a formal procedure for notifying regulators when the scope of an audit changes, particularly when it involves adding or substituting a technical activity. Also, revise Section 2.1 of the Audit Report to indicate that DR/CT was originally in the scope of A-03-13 but was subsequently removed.

5. It is unclear how the Permittees expect NMED to evaluate and approve waste characterization activities for S3000 homogeneous solid wastes as presented in the Audit Report. For example, Section 5.2.1 states, "Although the processes were verified, the demonstration of AK confirmation, DQOs reconciliation, preparation of a WSPF, and the transmittal of data to WIPP for the S3000 homogeneous solid waste will be verified at a later date." Similarly, Section 5.2.2 states, "S3000 sampling operations (e.g., specific container selection, sample collection, sample chain-of-custody, analytical laboratory sample analysis) will be evaluated at a later date and no S3000 waste will be shipped to WIPP until successful implementation and CBFO verification of these activities has occurred." Similar statements are found in the transmittal letter for the Audit Report. Please clarify whether these activities will be evaluated in a future audit and if the Permittees will submit additional objective evidence prior to seeking NMED approval for homogeneous solid waste characterization activities. As it stands now, the audit report does not support approval for homogeneous waste characterization because critical elements of the characterization program were not audited.

6. Procedures CCP-AK-ANLE-001, Rev. 7 (CCP AK Summary Report for ANL-E Contact Handled TRU Waste, Facility Maintenance and Laboratory Operations) and CCP-PO-001, Rev. 5 (CCP Transuranic Waste Characterization Quality Assurance Project Plan [**QAPjP**]) were not included in the CD 'Hot Burn'. Although the AK Summary report is included in Tab AK1, the QAPjP is not included in the Audit Report. This is inconsistent with the B6 Checklists, which frequently cite these documents.

7. Tables 5, 6, and 7 of the procedure CCP-AK-ANLE-001, Rev. 7 (pages 73 through 79 of 88 pages) of the objective evidence of CAR2 of the Audit Report have some problems in it. These tables were constructed as guidelines of *possible* waste codes in the evaluation of code assignment, as well as prohibited items recognition. Some of the chemicals listed in the table (Acetone, Methanol, Xylene, Benzene, Toluene, Toluene-d8, Ethyl ether, and Nitrobenzene) should also have identified D001 as a

possible RCRA code. In addition, the codes of U002 for Acetone, U019 for Benzene, U117 for Ethyl ether, U169 for Nitrobenzene, and U220 for Toluene and Toluene-d8 should have been added to the tables. The tables are incomplete and a concern during the audit should have been written.

8. A document in Tab GEN33 (a "Memo To File" from Tom Krause, dated 06.14.02) has a typographical error in item number one: it currently read F-155 and should read Fe-155. This misleads the reader into believing that Fluoride (F) is the topic of discussion, whereas Iron (Fe) is the topic.

B6 Checklist comments

In general, the B6 checklist suffers from lack of specificity in numerous items, as noted below:

9. General comment, procedure revision references – despite the fact that there may have been procedure revisions between Audits A-02-03 and A-03-13, ensure that all procedure references on the B6 checklists cite the final revision provided in the Audit Report. If there is a specific need to cite an earlier revision, provide complete justification.

10. B6 Checklist, Item 12 – the exact locations of parts C and I are not specifically identified in procedures CCP-TP-039, Rev. 6 and CCP-TP-031, Rev. 12.

11. B6 Checklist, Item 12 – there is no comparable correlation between the remaining sub items (e.g., A, B, D, etc.) and the cited procedures (e.g., CCP-TP-005, Rev. 11, etc.).

12. B6 Checklist, Item 13 – the exact locations are not specifically identified in procedures CCP-TP-039, Rev. 6 and CCP-TP-031, Rev. 12.

13. B6 Checklist, Item 17 – the exact location is not specifically identified in procedure CCP-TP-056, Rev. 1

14. B6 Checklist, Item 18 – the exact locations are not specifically identified in procedures CCP-TP-039, Rev. 5, CCP-TP-031, Rev. 10, and CCP-TP-034, Rev. 7

15. B6 Checklist, Item 21 – the exact locations are not specifically identified in procedures CCP-TP-039, Rev. 6 and CCP-TP-031, Rev. 12

16. B6 Checklist, Item 33 – the exact location is not specifically identified in procedure CCP-TP-034, Rev. 9. Also, Items 32 and 33 reference CCP-PO-001, Rev. 5, Sec. B1-3b, but should this reference instead be Section B3-10?

17. B6 Checklist, Item 34 – the exact location is not specifically identified in procedure CCP-TP-034, Rev. 9

18. B6 Checklist, Item 38 – there should be a comment to explain why parts D and E are Not Applicable (NA).

19. B6 Checklist, Item 44 – the exact locations are not specifically identified in procedures CCP-QP-005, Rev, 7 and CCP-QP-006, Rev. 4.

20. B6 Checklist, Item 45 – the exact locations are not specifically identified in procedures CCP-QP-005, Rev. 7, CCP-QP-006, Rev. 4, and CCP-QP-004, Rev. 4.

21. B6 Checklist, Items 50, 51, and 52 – the exact location is not specifically identified in procedure CCP-TP-030, Rev. 7.

22. B6 Checklist, Item 60 – the two stated sections of CCP-TP-002, Rev. 11 don't appear to address the requirement to submit waste stream summary information and reconciliation of DQOs to the WIPP facility. Section 4.5 seems to address this item.

23. B6 Checklist, Item 67 – there is no Sec. 4.9.10 (Note) in procedure CCP-QP-008, Rev. 8. This may be a typographical error and the location may be CCP-QP-008, Rev. 8, Sec. 4.10 (Note).

24. B6 Checklist, Item 69 – there is no Sec. 4.9.5.B in procedure CCP-QP-008, Rev. 8.

25. B6 Checklist, Item 71 – CCP-QP-008, Rev. 8, Section 2.3.6 is OK, but Section 4.10.6 [D] seems to address the WAP requirement more specifically.

26. B6 Checklist, Items 72 and 73 – the exact location is not specifically identified in procedure CCP-TP-030, Rev. 7.

27. B6 Checklist, Item 143 – CCP-TP-005, Rev. 11, Section 4.2 is cited. Shouldn't section 4.4 be cited instead of 4.2?

28. B6 Checklist, Item 148 – the exact location is not specifically identified in procedure CCP-QP-002, Rev. 11.

29. B6 Checklist, Item 151 – the exact locations are not specifically identified in procedures CCP-TP-005, Rev. 11; CCP-PO-002, Rev. 4; CCP-PO-008, Rev. 3; CCP-PO-009, Rev. 4; CCP-QP-002, Rev. 11; CCP-QP-004, Rev. 3; CCP-QP-005, Rev. 6; and CCP-QP-006, Rev. 3. Also, procedures CCP-PO-008 and CCP-PO-009 do not appear on the list of audited procedures.

30. B6 Checklist, Item 168 – there is mention of a *draft* accuracy report (AK-46). Should a final accuracy report be submitted as an amendment to the Audit Report in the future, or will this be the subject of a subsequent recertification audit?

31. B6 Checklist, Items 171 through 177 – the exact locations are not specifically identified in procedures CCP-QP-018, Rev. 2, CCP-QP-019, Rev. 1, CCP-QP-020,

Rev. 2, and CCP-QP-021, Rev. 3. Also, procedures CCP-QP-018, -019, -020, and -021 do not appear on the list of audited procedures.

32. B6 Checklist, Item 181 – the exact location is not specifically identified in procedure CCP-TP-005, Rev. 8.

33. B6 Checklist, Item 208 – the exact locations are not specifically identified in procedures CCP-TP-031, Rev. 10 and CCP-TP-031, Rev. 12. In addition, why are two revisions cited to answer the question? Was there a significant change in this and other procedures between audits A-02-03 and A-03-13 that warranted the separate citations? This question regarding different revisions applies to numerous other items on the B6-4 Headspace Gas Checklist as well.

34. B6 Checklist, Item 230 – the exact locations are not specifically identified in procedures CCP-TP-034, CCP-TP-031, and CCP-TP-039.

35. B6 Checklist, Item 235 – CCP-TP-045 does not seem to address the WAP requirement.

36. B6 Checklist, Item 239 – the exact locations are not specifically identified in procedures CCP-TP-045, Rev. 6, CCP-TP-028, Rev. 1, and CCP-PO-001, Rev. 4. As noted earlier, procedure CCP-PO-001 does not appear on the list of audited procedures.

37. B6 Checklist, Item 294 – since the UCL_{90} has not yet been established, should such a calculation be amended to the Audit Report in the future, or will this be the subject of a subsequent recertification audit? Also, there is no mention of the binomial distribution.